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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,312	02/15/2002	John McKenzie	271/094	3792

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,312	MCKENZIE ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-12* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 6/21/05 has been entered. Claims 1-3 and 6-12 are currently pending, of which claim 11 remains withdrawn from consideration for being drawn to a non-elected species. The claims being considered for further examination on the merits are claims 1-3, 6-10 and 12.

Response to Arguments

2. Applicant's arguments, see the third paragraph under "Art Rejections" in the REMARKS section, filed 6/21/05, with respect to the rejection(s)of claim(s) 1-3, 6-10 and 12 under 35 U.S.C. 103(a) by Bajaj (USPN 5,053,008) in view of Kletschka (USPN 4,794,928) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Tsugita et al. (USPN 5,911,734) and Barbut et al. (USPN 5,662,671).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 8 is indefinite because it requires a "second perfusion lumen" without requiring a first perfusion lumen. Because the claim is dependent on claim 7, it appears that "perfusion lumen" should be --infusion lumen--, and will so be interpreted for examination purposes.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 2, 6-8, 10 and 12 are rejected under 35 U.S.C. 103(a) as being obvious over Tsugita et al. (USPN 5,911,734) in view of Barbut et al. (USPN 5,662,671).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Tsugita et al. discloses a catheter apparatus with all the elements of claim 1, but is silent to the upstream member being a sealing member for creating a seal between the upstream end of the expandable conduit and an internal wall of the body passage. See Figure 13 for an expandable conduit (50) defined by a filter mesh (60) (column 5, lines 11-15; "instead of having a closed end" clearly indicates that the end is open, therefore providing a structure with two open ends, which is a conduit by definition) mounted on a catheter shaft (12) (column 15, lines 20-25). As admitted by applicant, the filter mesh will inherently have varying porosity. See Figure 13 for the expandable conduit (50) having an upstream end (64) and a downstream end (62). While the downstream end (62) is "attached to the outer surface 13 of the catheter 12" (column 15, lines 22-24), the end is still structurally open because it allows for fluid flow therethrough via the catheter lumen. The expandable conduit (50) has a collapsed position in which the expandable conduit is collapsed toward the catheter shaft (12) and an expanded position in which the upstream end (64) of the expandable conduit (50) is open to fluid flow (column 15, lines 20-33). See Figure 13 for an upstream member (102) being at the upstream end (64) of the expandable conduit (50). Barbut et al. teaches a sealing member (70) at the upstream end of a expandable conduit filter mesh (75), wherein the sealing member (70) prevents leakage around the seal in order to filter substantially all the blood flowing downstream. See Figure 1, column 6, lines 14-16 and column 13, lines 9-12 and 44-48. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Barbut et al. to modify the upstream member (102) of Tsugita et al. by making it a sealing member for preventing leakage

around the seal in order to filter substantially all the blood flowing downstream. The sealing member will create a seal between the upstream end (64) of the expandable conduit (50) and internal wall (72) of the body passage (70).

Claim 2, see column 14, lines 47-49 for the upstream member being an inflatable toroidal balloon (102).

Claim 6, see Figure 13 for an occlusion member (16) for selectively occluding the expandable conduit (50).

Claims 7 and 8, see Figure 13 and column 14, lines 44-47 for an infusion lumen (18) and a second infusion lumen (19), as interpreted by the examiner, within the catheter shaft (12).

Claim 10, see column 14, line 45 for the occlusion member (16) being an inflatable occlusion balloon.

Claim 12, see Figure 13 for the catheter shaft (12) being positioned internal to the expandable conduit (50).

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. and Barbut et al. as applied to claim 1 above, and further in view of Bajaj (USPN 5,053,008, as cited in applicant's IDS).

Tsugita et al., as modified by Barbut et al., discloses a catheter apparatus with all the elements of claim 1, but is silent to a perfusion lumen within the catheter shaft in fluid communication with a space exterior to the expandable conduit, as required by claim 3. Bajaj teaches a catheter apparatus for use in a body passage, wherein thrombolytic agents (66) are perfused through a catheter perfusion lumen (64) in order to lyse a clot in a vessel. See Figure 2

and column 9, lines 35-39. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bajaj to modify the catheter shaft of Tsugita et al. by including a perfusion lumen therein in fluid communication with a space exterior to the expandable conduit (50) in order to pass thrombolytic agents and lyse the clot within the vessel.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita et al. in view of Kletschka (USPN 4,794,928, as cited in previous office action).

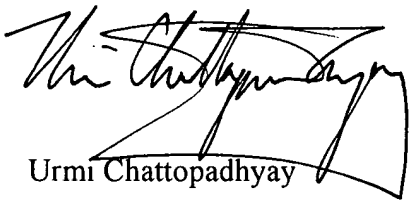
Tsugita et al. discloses a catheter apparatus with all the elements of claim 1, but is silent to the upstream member being a sealing member for creating a seal between the upstream end of the expandable conduit and an internal wall of the body passage. See Figure 10 for an expandable conduit (50) defined by a filter mesh (60) mounted on a catheter shaft (12) (column 13, lines 42-44). As admitted by applicant, the filter mesh will inherently have varying porosity. See Figure 10 for the expandable conduit (50) having an upstream end (64) and a downstream end (62). While the downstream end (62) is "attached directly to the outer surface 13 of the catheter 12" (column 13, lines 51-52), the end is still structurally open because it allows for fluid flow therethrough via the catheter lumen. The expandable conduit (50) has a collapsed position in which the expandable conduit is collapsed toward the catheter shaft (12) and an expanded position in which the upstream end (64) of the expandable conduit (50) is open to fluid flow. A tubular sheath (132) is sized to fit over the expandable conduit (50) when in the collapsed position. See column 14, lines 1-12. Members (54) are positioned at the upstream end (64) of the expandable conduit (50) and are radially biased to engage the walls (72) of the blood vessel

(70). Kletschka teaches a trap/barrier membrane (23) with radially biased expansion springs (18), wherein expansion of the springs (18) causes the trap/barrier membrane (23) to seal with the interior lining of a vessel. See Figures 12 and 14, column 7, lines 29-42 and columns 8-9, lines 52-10. This seal prevents substantially all physiologically significant particles from escaping from an obstruction site and removes substantially all potential embolic material. See column 2, lines 36-40. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kletschka to modify the upstream members (54) of Tsugita et al. by making them sealing members in order to prevent substantially all physiologically significant particles from escaping from an obstruction site and remove substantially all potential embolic material. The members will create a seal between the upstream end (64) of the expandable conduit (50) and internal wall (72) of the body passage (70).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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